UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,947	09/12/2003	Charles Eric Mowbray	PC25375A	8400

28940 7590 05/31/2006

AGOURON PHARMACEUTICALS, INC.
10777 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER	
GRAZIER, NYEEMAH	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,947	MOWBRAY ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-19* is/are pending in the application.

4a) Of the above claim(s) *9-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8 and 19* is/are rejected.

7)☐ Claim(s) *5-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION
NON-FINAL OFFICE ACTION

I. ACTION SUMMARY

The Amendments to the Claims and Remarks submitted to the Office on March 10, 2006 has been fully considered and will be the basis of the following Action.

Claims 1, 2, 5-19 are currently pending. Claims 9-19 are withdrawn. Claims 3 and 4 have been canceled.

II. RESPONSE TO AMENDMENTS

A. Restriction/Election

Applicant's confirm the telephonic provisional election of specie and request that the method claim are rejoined upon determining that the application is in condition for allowance. See Remarks, p. 9 or 13. The election was made with traverse, however the grounds of traversal was not identified in the Reply filed March 10, 2006.

The restriction requirement is deemed proper and is therefore made FINAL.

B. *35 USC §103*

Applicant's arguments, see Remarks, filed March 10, 2006, with respect to claim rejections (1-8 and 19) under 103 have been fully considered. Applicant argues that Jones et al. (the '860 publication) is not available as a proper reference and is therefore inapplicable and invalid as a 103 reference. See Remarks, p. 9. The argument is not persuasive because although Applicants are correct in asserting that the publication date of the prior art is October 31, 2002 and that the instant application claims priority to foreign application filed on September 16, 2002, the instant invention was subject to an obligation of assignment to Pfizer Ltd., the same

entity as the '860 Publication, at the time this invention was made. The '860 Publication additionally qualifies as prior art under another subsection of 35 U.S.C. 102 (e.g. 102(e), and therefore, is not disqualified as prior art under 35 U.S.C. 103(c). Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131. Thus, the 102(e) date is sufficient to maintain the 103 rejection.

Applicants assert that the 103 rejection should be withdrawn because the argument uses assertions from "improper picking and choosing of substituents." The argument is persuasive with respect to the '424 Publication. All of the variables are not taught in the preferred embodiments. The rejection based on the '424 Publication is ***withdrawn.***

C. Objection to Claims under 37 CFR 1.75

Claims 3, 5, and 7 and 4, 6 and 8 stand objected to an being substantial duplicates. Applicant's arguments submitted on March 10, 2006 was not responsive to this issue. Claims 4 and 4 have been canceled and therefore objections of claims 4 and 5 are now moot. However, the ***objections of claims 5-8 are maintained.***

D. Objection to the Specification

Applicant's arguments, see Remarks, filed March 10, 2006 have been fully considered and are persuasive in light of the Amendment. Thus, the objection has been obviated.

III. REJECTIONS

Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Jones et al, WO 02/085860 A1 at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference Jones et al, WO 02/085860 A1 additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

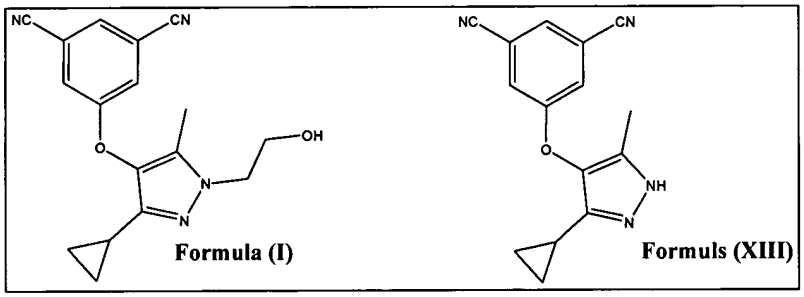
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jones et al, WO 02/085860 A1 (hereinafter referred to a "the WO '860 publication").

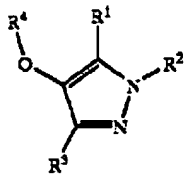
First, Instant **Claim 1** recites a compound of Formula (I) or a pharmaceutically acceptable salt, solvate or derivative thereof. Next, **Claim 3, 5, and 7** recite "a compound according to claim 1" wherein the compound claims an intended use. Lastly, **Claim 19** recites a compound of Formula (XIII). The following are structures of Formula (I) and (XIII) as described in the instant application.

Furthermore, **Claim 2** recites "[A] pharmaceutical composition comprising the compound according to claim 1 and one or more pharmaceutically acceptable excipients, diluents or carriers." **Claims 4, 6 and 8** depend from Claim2 wherein the invention as recited is "a composition according to Claim 2" for a specified intended use.



(1) Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The '860 publication teaches a the compound of Formula (I),



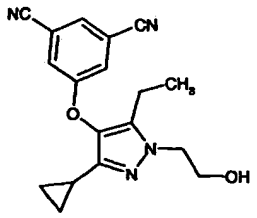
wherein R1 is methyl, R2 may represent –CH2CH2OH or hydrogen, R3 is cyclopentyl, and R4 is 3,5-dicyanophenyl to afford a compound inherently similar to the Formula (I) of the instant invention. (See e.g., WO 02/085860 A1, pp. 5-8).

(2) Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The single difference between the prior art of the '860 publication and the instantly claimed inventions is in scope. Both inventions teach the same utility and have the same structural core. The '860 publication is broader in scope than the instant invention. However, he '860 publication teaches a preferred embodiment of the invention which includes the specie of the instant invention. See pp. 5-8. Lastly, the '860 publication discloses the method of making and using a homolog of the instant invention in one of the enumerated examples. See, Example 168 at p. 133.

EXAMPLE 168

5-[[3-Cyclopropyl-5-ethyl-1-(2-hydroxyethyl)-1*H*-pyrazol-4-yl]oxy]isophthalonitrile



The difference between the specie of the '860 publication and the instant invention is the substituent on the 5 position of the pyrazolyl ring. The instant invention is drawn to 5-methyl pyrazolyl while the '860 publication is drawn to a 5-ethyl pyrazolyl.

(3) Finding of Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The prima facie case for obviousness is derived from the preferred teaching of the reference. The reference teaches preferred compounds and preferred variable substituents. For example, R1 is preferably –CH3 (*Jones et al.*, p.5, l. 37); R2 is preferably H or –CH2CH2OH (*Jones et al.*, p. 7, l. 5); R3 is preferably cyclopropyl *(Jones et al.*, p. 7, l. 29); and R4 is preferably 3,5-dicycanophenyl, p. 8 ll. 1-2). Thus, the teachings of the *Jones et al.* reference would have motivated one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Additionally, members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed by the prior art. In re Hass, 60 USPQ 548 (CCPA 1944). The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

Provisional Obviousness-Type Double Patenting

Claims 1, 2 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-15, 29, 31, 46, and 47 of copending Application No. 10/118,512 (US 2003/0100554A1). This is a provisional

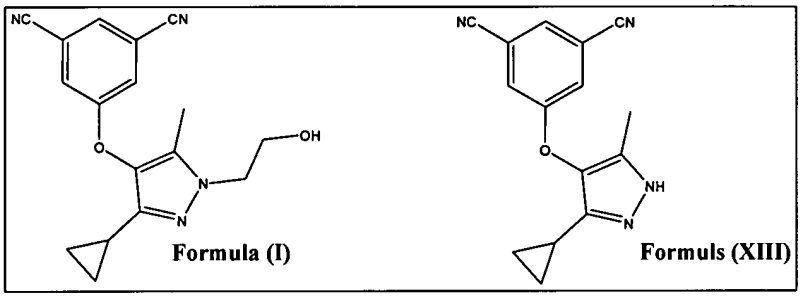
obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re* Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re* Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re* Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re* Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). See also M.P.E.P. § 804 (2001).

Obvious-type nonstatutory double patenting rejection is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103" with the distinction that the double patent rejection is not considered prior art. Id. See also In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Thus, the analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

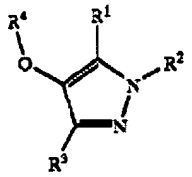
First, Instant **Claim 1** recites a compound of Formula (I) or a pharmaceutically acceptable salt, solvate or derivative thereof. Next, **Claim 3, 5, and 7** recite "a compound according to claim 1" wherein the compound claims an intended use. Lastly, **Claim 19** recites a compound of Formula (XIII). The following are structures of Formula (I) and (XIII) as described in the instant application.

Furthermore, **Claim 2** recites "[A] pharmaceutical composition comprising the compound according to claim 1 and one or more pharmaceutically acceptable excipients, diluents or carriers." **Claims 4, 6 and 8** depend from Claim2 wherein the invention as recited is "a composition according to Claim 2" for a specified intended use.



(1) Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The '860 publication teaches a the compound of Formula (I),



wherein R1 is methyl, R2 may represent –CH2CH2OH or hydrogen, R3 is cyclopentyl, and R4 is 3,5-dicyanophenyl to afford a compound inherently similar to the Formula (I) of the instant invention. (See e.g., WO 02/085860 A1, pp. 5-8).

(2) Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The single difference between the prior art of the '860 publication and the instantly claimed inventions is in scope. Both inventions teach the same utility and have the same structural core. The '860 publication is broader in scope than the instant invention. However, he

'860 publication teaches a preferred embodiment of the invention which includes the specie of the instant invention. See pp. 5-8. Lastly, the '860 publication discloses the method of making and using a homolog of the instant invention in one of the enumerated examples. See, Example 168 at p. 133.

The difference between the specie of the '860 publication and the instant invention is the substituent on the 5 position of the pyrazolyl ring. The instant invention is drawn to 5-methyl pyrazolyl while the '860 publication is drawn to a 5-ethyl pyrazolyl.

Resolving Level of Ordinary Skill in the Pertinent Art

The pertinent art is immunology. Specifically, the invention is useful in th e treatment of Human Immunodeficiency Virus ("HIV"). One of ordinary skill in the pertinent art of immunology would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teach compounds useful for treatment of HIV. The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The prima facie case for obviousness is derived from the preferred teaching of the reference. The reference teaches preferred compounds and preferred variable substituents. For example, R1 is preferably –CH3 (*Jones et al.*, p.5, l. 37); R2 is preferably H or –CH2CH2OH (*Jones et al.*, p. 7, l. 5); R3 is preferably cyclopropyl *(Jones et al.*, p. 7, l. 29); and R4 is preferably 3,5-dicycanophenyl, p. 8 ll. 1-2). Thus, the teachings of the *Jones et al.* reference would have motivated one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Additionally, members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed by the prior art. In re Hass, 60 USPQ 548 (CCPA 1944). The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

VI. CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

Nyeemah Grazier, Esq.
Patent Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-8781

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph K. McKane
Supervisory Primary Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-0699